MANAGEMENT PROCEDURE



Carlsbad Area Office

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Revision 2

Title: SURVEILLANCES

Manager, Carlsbad Area Office Aching

Date: 9/4/18

1.0 PURPOSE

The purpose of this procedure is to define the process, responsibilities and controls that Carlsbad Area Office (CAO) personnel shall observe when planning and conducting quality assurance (QA) and technical surveillances.

2.0 SCOPE

This procedure specifies the methods for scheduling, performing, reporting, and closing CAO surveillances of activities performed in accordance with the CAO Quality Assurance Program Document. This procedure supersedes MP 10.2, Revision 1, Surveillances.

3.0 REFERENCES AND DEFINITIONS

3.1 References

- 3.1.1 DOE CAO Quality Assurance Program Document (QAPD) CAO-94-1012
- 3.1.2 CAO Management Procedure (MP) 3.1, Corrective Action Reports
- 3.1.3 CAO MP 4.9, Quality Assurance Records
- 3.1.4 CAO MP 10.3, Audits

3.2 Definitions

- 3.2.1 <u>Responsible Team Leader (RTL)</u> The CAO team leader whose area of responsibility encompasses the activity being assessed.
- 3.2.2 <u>Condition Adverse to Quality (CAQ)</u> An all-inclusive term used in reference to failures, malfunctions, deficiencies, defective items, nonconformances, and technical inadequacies.
- 3.2.3 <u>Corrective Action</u> Measures taken to rectify conditions adverse to quality and, where necessary, to preclude recurrence.
- 3.2.4 <u>Corrective Action Report (CAR)</u> A document used to identify and document actions taken to correct and preclude recurrence of conditions adverse to quality.
- 3.2.5 Observations Conditions that, if not controlled, could escalate into a CAQ.
- 3.2.6 <u>Recommendations</u> Suggestions that are directed toward identifying opportunities for improvement and enhancing method of implementing requirements.

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- 3.2.7 <u>Surveillance</u> The act of monitoring or observing to verify whether an item, activity, system, or process conforms to specified requirements. Surveillance of a work activity is normally done in real time, i.e., the surveillance is accomplished as the work is being performed.
- 3.2.8 <u>Surveillance Team Leader (STL)</u> The person designated to plan, lead, and report the conduct of a surveillance.
- 3.2.9 <u>Technical Specialist</u> An individual assigned to an assessment team when the scope, complexity, or special nature of the work to be examined warrants assessment of the technical adequacy of the work.

4.0 **RESPONSIBILITIES**

4.1 Manager, Carlsbad Area Office (CAO)

The CAO Manager has the responsibility to approve the CAO assessment schedule, including scheduled surveillances.

4.2 Assistant Managers

Assistant managers have the responsibility of providing input to the team leaders within their organization on proposed surveillance schedules.

4.3 Responsible Team Leaders

The team leaders have responsibility for:

- 4.3.1 Identifying activities under their direction for surveillance.
- 4.3.2 Scheduling the surveillance and notifying the Quality Assurance Manager for incorporation in the CAO assessment schedule.
- 4.3.3. Selecting the surveillance team leaders.
- 4.3.4 Reviewing and concurring with the appointment of team members to participate in the surveillances.
- 4.3.5 Notifying the organization to be surveilled.
- 4.3.6 Reviewing and issuing surveillance reports to evaluate the effectiveness of the surveilled activity.
- 4.3.7 Assuring that corrective action reports are initiated when results of surveillance identify conditions adverse to quality.

4.4 Quality Assurance Manager

The Quality Assurance Manager (QAM) has additional responsibility for:

- 4.4.1 Coordinating with CAO team leaders to include surveillances in the CAO assessment schedule.
- 4.4.2 Assessing the effectiveness of the surveillance activities conducted by CAO organizations.
- 4.4.3 Assuring that corrective action reports are incorporated in the tracking system.

4.5 Surveillance Team Leader

The surveillance team leader has responsibility for:

- 4.5.1 Identifying the personnel requirements for the surveillance, selecting and assembling the team members, requesting quality assurance and technical specialist support as necessary, and coordinating concurrence of the team selection with the responsible team leader.
- 4.5.2 Ensuring that the surveillance team members are qualified and suitably trained for the performance of the surveillance.
- 4.5.3 Designating the methods that will be used to obtain and document objective evidence during the surveillance.
- 4.5.4 Conducting the surveillance.
- 4.5.5 Coordinating the resolution of emergent issues and providing guidance to the surveillance team as necessary during the conduct of the surveillance.
- 4.5.6 Preparing the surveillance report in accordance with this procedure and any corrective action reports in accordance with MP 3.1.
- 4.5.7 Assuring that QA records generated as a result of the surveillance are submitted in accordance with MP 4.9.

4.6 Surveillance Team

Members of the surveillance team have responsibility for:

- 4.6.1 Preparing the surveillance checklists, as directed, or implementing the method selected by the surveillance team leader, to guide the surveillance and document results.
- 4.6.2 Conducting the surveillance, as directed by the surveillance team leader.
- 4.6.3 Providing the surveillance team leader with the results of the surveillance, including any conditions adverse to quality, completed checklists if used, or another method of documenting results selected by the surveillance team leader.
- 4.6.4 Assisting the surveillance team leader with the preparation of the surveillance report and any required corrective action reports, as requested.

5.0 PROCEDURE

5.1 Planning/Scheduling

- 5.1.1 Surveillances are conducted to evaluate the quality of work subject to the CAO Quality Assurance Program Document (QAPD) and other requirements. CAO team leaders determine the need for surveillances by considering the following:
 - a. The need to verify quality or technical adequacy of work in progress and, when necessary, identify conditions adverse to quality.
 - b. The need to verify timely implementation of corrective action.

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- 5.1.2 The team leaders shall provide input to the Quality Assurance Manager for inclusion of the scheduled surveillances in the CAO assessment schedule.
- 5.1.3 The team leaders shall ensure that surveillances are appropriately planned and scheduled for their areas of responsibility.
- 5.1.4 The responsible team leader shall select the surveillance team leader, and make recommendations to the surveillance team leader for a team composition that provides the levels of experience and technical expertise commensurate with the scope and complexity of the activity to be surveilled.

5.2 Preparation

- 5.2.1 If there are two or more members of the surveillance team, the surveillance team leader shall review the training and experience of the prospective surveillance team members to verify that they are adequately qualified to participate in the surveillance. The surveillance team leader will also review the surveillance logistics with the team.
- 5.2.2 The responsible team leader should notify the organization to be surveilled, either verbally or in writing.
- 5.2.3 The surveillance team should develop a checklist for the activity to be surveilled (see attachment I), or use any other method selected by the surveillance team leader to guide the surveillance and document the results (e.g., the use of a procedure annotated with steps evaluated, the identification of the objective evidence that was reviewed, and the results).

5.3 Performance

- 5.3.1 The surveillance team leader may conduct a pre-surveillance meeting to reinforce the purpose and scope of the surveillance and to introduce the surveillance team.
- 5.3.2 The surveillance team shall:
 - a. Observe the activity in progress and review documentation to determine if the item, activity, system, or process conforms to specified requirements.
 - b. Record the names of personnel interviewed, the activities observed, the documentation reviewed, and results on the checklist (or other document, if a checklist is not used). Any conditions adverse to quality, including those corrected during the surveillance; any observations; any recommendations; and any occurrences of exemplary practices shall also be recorded.
 - c. Document and process conditions adverse to quality in accordance with MP 3.1.
- 5.3.3 If corrective action reports are necessary, the surveillance team leader shall conduct a post-surveillance meeting to present results to the appropriate management of the surveilled organization; otherwise, the meeting is optional.

5.4 Reporting

- 5.4.1 The surveillance team and/or surveillance team leader shall document and process conditions adverse to quality in accordance with MP 3.1. The surveillance team shall provide documentation of surveillance activities to the surveillance team leader.
- 5.4.2 The surveillance team leader shall prepare a surveillance report (see attachment II).

- 5.4.3 The surveillance report shall be signed by the surveillance team leader, and forwarded to the responsible team leader for concurrence and issuance.
- 5.4.4 Copies of the approved surveillance report shall be distributed to the following:
 - a. The organization surveilled
 - b. The responsible assistant manager
 - c. The Quality Assurance Manager
 - d. The surveillance team leader

5.5 Closure

- 5.5.1 The surveillance is considered closed upon issuance of the surveillance report.
- 5.5.2 QA records generated as a result of the surveillance shall be submitted in accordance with MP 4.9.

6.0 RECORDS

Surveillance reports and completed checklists or objective evidence of the surveillance, as stated in paragraph 5.2.3, shall be processed and maintained as QA records in accordance with MP 4.9.

7.0 ATTACHMENTS

- Attachment I Example of a Completed Surveillance Checklist
- Attachment II Surveillance Report (Example)
- Attachment III Surveillance Process Flow Chart

ATTACHMENT I
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EXAMPLE OF A COMPLETED SURVEILLANCE CHECKLIST

CAO SURVEILLANCE CHECKLIST

Organization Evaluated: National TRU Program Surveillance Number: S-97-14

Activities Evaluated: Surveillances Date of Surveillance: 4/18/97

Controlling Documents: MP 10.2, Revision 1

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Item No.	Characteristic(s)	Objective Evidence	*Results
1	Verify that surveillance report and completed checklists, if used, are maintained as QA records. (Paragraph 6.0)	Reviewed the following surveillance reports and checklists submitted to the Project Record Services. There were a total of 5 surveillance performed to date. 1. S-96-39 2. S-97-01	SAT

^{*} Indicate Results: Satisfactory (SAT), Unsatisfactory (UNSAT), Not Applicable (NA), Indeterminate (I)

ATTACHMENT II
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SURVEILLANCE REPORT (Example)

U.S. DEPARTMENT OF ENERGY CARLSBAD AREA OFFICE

SURVEILLANCE REPORT

OF

[Surveilled Organization]

[Organization Location]

SURVEILLANCE S-YY-XX

[Dates of the Surveillance]



PRIMARY ACTIVITY EVALUATED

Prepared by:		Date:	
	Surveillance Team Leader		
Issued by:		Date:	
	Responsible Team Leader		

ATTACHMENT II
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1.0 EXECUTIVE SUMMARY

CAO Surveillance S-YY-XX was conducted to evaluate the adequacy and effectiveness of (describe the primary activity or process evaluated). The surveillance was conducted at (location) from (dates). The surveillance team consisted of personnel from (organization(s)). The surveillance team determined that (summarize the overall result). (Number) deficiencies were identified, resulting in (number of) corrective action report(s) (CAR/CAR's) that require corrective action in the areas of (identify deficient areas). (Number) deficiency(ies) that was/were isolated in nature, (was/were) corrected and verified during the surveillance in the areas (describe areas). In addition, (number of) recommendation(s) are identified in section 6 of this report.

(Discuss in brief any additional information, such as exemplary practices.)

2.0 SCOPE

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CAO Surveillance S-YY-XX was conducted to evaluate the (adequacy, implementation, and/or effectiveness as appropriate) of (describe the activity or process evaluated).

3.0 SURVEILLANCE TEAM AND OBSERVERS

The surveillance team, including observers, consisted of the following personnel: (list names, organizations, and titles).

4.0 SURVEILLANCE PARTICIPANTS

The following personnel were contacted during the course of the surveillance: (list names, organizations, and titles. If a substantial number of personnel were contacted, a table may be developed as an attachment to the surveillance report.)

5.0 SURVEILLANCE DETAILS

(Describe the details of the surveillance in concise terms. Sufficient detail must be provided for technical areas to demonstrate that the methodology used and evidence reviewed adequately supports the effectiveness determination. If information is extensive, consider the use of a summary table as an attachment for the surveillance

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	details and the objective recommended format.)	e evidence reviewed.	See MP 10.3	s, <i>Audits</i> , for a	
6.0	ATTACHMENTS				
	(List attachments)				

ATTACHMENT III

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SURVEILLANCE PROCESS

